



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-24		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP 03/05327		International filing date (day/month/year) 25.04.2003	Priority date (day/month/year) 30.04.2002
International Patent Classification (IPC) or both national classification and IPC A61J1/10			
Applicant OTSUKA PHARMACEUTICAL FACTORY, INC. et Al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 5 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 22.09.2003		Date of completion of this report 29.06.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Godot, T Telephone No. +31 70 340-3319 	

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International application No. **PCT/JP 03/05327**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-25 as originally filed

Claims, Numbers

1, 3, 5-16 received on 03.12.2003 with letter of 28.11.2003

Drawings, Sheets

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1,5-8,13,14
	No: Claims	3,9-12,15,16
Inventive step (IS)	Yes: Claims	
	No: Claims	1,3,5-16
Industrial applicability (IA)	Yes: Claims	1,3,5-16
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-4 602 910 (LARKIN MARK E) 29 July 1986 (1986-07-29)

D2: EP-A-0 639 364 (OTSUKA PHARMA CO LTD) 22 February 1995 (1995-02-22)

2. The document D1 discloses (see col. 2, line 67 to col. 4, line 55; the references in parentheses applying to this document):

A multiple-chamber medical container (10) comprising:

a container body having the chambers (*first chamber 11, second chamber surrounding small "container" 34*) for containing medicaments (51) therein and a partitioning seal portion (44) for separating the chambers from one another,

a medicinal outlet portion (25,26) attached to the container body for discharging the medicaments from the chambers therethrough,
and

an openable small container (34) disposed in at least one of the chambers and having a medicament (50) enclosed therein;

the partitioning seal portion (44) being openable (*sealed area 40 breaks after weak seal 43 of inner container 34 has been broken, see col. 4, lines 9-21*) so as to cause the chambers to communicate with one another for use,

the partitioning seal portion (44) is formed by bonding opposed inner wall surfaces (15,18) of the container body separably (*inner wall surfaces are bonded by means of walls 36,37 and weak seals 40,40 and 43*),

the sheet material (36,37) forming the small container (34) being bonded to the inner wall surfaces of the container body within the partitioning seal portion (44) (*present claim 3 I*),

the small container (34) opening in accordance with the separation of the inner wall surfaces caused by opening the partitioning seal portion (44).

Hence, the subject-matter of independent claim 3 is not new in the sense of Article 33(2) PCT.

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3. The subject-matter of claim 1 differs from the subject-matter of claim 3 and therefore from the disclosure of D1, only in that the sheet material forming the small container is bonded to the opposed inner wall surfaces of the container body in the vicinity of the partitioning seal portion.

However, this difference cannot be considered to involve an inventive step because it is generally known to the person skilled in the art that the feature of binding the small container in the vicinity of the seal portion is an equivalent to the feature of binding the small container within the seal portion of document D1 and can be interchanged with that feature where circumstances make it desirable.

4. Claim 16 is considered as an independent claim because it specifies only a bag which is *suitable for* enclosing a multiple-chamber container. Such a bag is known from D1 (see col. 3, lines 60-66), or from D2 where it encloses a folded multi-chamber container (see col. 11, line 55 to col. 12, line 3).

The subject-matter of independent claim 16 is therefore not new in the sense of Article 33(2) PCT.

5. Dependent claims 5-15 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step. See for example:

D1, col. 2, line 67 to col. 4, line 61 for claims 5-12,15.

By changing the position of the medicinal outlet portion, claim 13 discloses only an obvious alternative of the embodiment disclosed in D1 and D2.

In claim 14, the wording "discharge-control seal portion" is so vague that it could correspond to a tab which is placed in the outlet port between the outlet portion and the chamber. Such a tab is well known in the field of medical containers and the skilled person would regard as a normal option to include a tab in the container described in document D1.